

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Initially, Applicants wish to express their appreciation to the Examiner for his courtesy and helpful suggestions provided to the Applicant's representative during the telephone interview held on October 8, 2003.

Claims 25, 27-28 and 33 are pending after the foregoing amendments. The remainder of the claims are cancelled without prejudice.

Claims 26 and 30 are rejected under 35 USC 112, first paragraph, for the reasons set forth on pages 2-3 of the Action.

This ground of rejection is deemed to be overcome in view of the cancellation without prejudice of these claims.

Claims 25-36 are rejected under 35 USC 103 as being unpatentable over Sakai et al. in view of Merck for the reasons set forth on pages 4-6 of the Action. This ground of rejection is respectfully traversed as applied to the foregoing claims.

The present claims 25, 27, 28 and 33 relate to a method for the prophylaxis or treatment of viral myocarditis.

Sakai et al. teach that 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol (hereinafter referred to as the present compound) is useful for the treatment or prevention of hepatic diseases such as acute liver necrosis (e.g., necrosis caused by toxins, viral hepatitis, shock or anoxia), viral hepatitis B, non-A/non-B hepatitis and cirrhosis, because it has a liver regenerating activity and/or an activity of promoting hypertrophy and hyperplasia of hepatocytes (see column 5, lines 28-40). In other words, the description of the usefulness of the present compound against viral hepatitis in Sakai et al. is based on the liver regenerating activity and activity of promoting hypertrophy and hyperplasia of hepatocytes of the present compound. Therefore, whether or not the present compound is effective for viral myocarditis (viral infection in heart muscle) is not suggested by Sakai et al.

The present inventors are the first to conceive and experimentally prove the effect of the present compound on viral myocarditis in disease models infected with virus. See the Experimental Examples in the present specification. The effect of the present compound against viral myocarditis could not be reasonably expected by those of ordinary skill in the art from the teachings of Sakai et al. Sakai et al. merely teach usefulness of the present compound against hepatic diseases based on the liver regenerating activity and activity of promoting hypertrophy and hyperplasia of hepatocytes that the present compound possesses.

Sakai et al. also disclose that the present compound is applicable to certain eye diseases, and recite conjunctivitis as an example of such eye diseases (see column 4, lines 53-54). In the meantime, the Merck Manual discloses that acute hemorrhagic conjunctivitis is associated with infection by enterovirus type 70. Enterovirus belongs to the family of picornavirus. However, conjunctivitis and viral myocarditis are two different diseases. Neither Sakai et al. nor the Merck Manual describe or suggest that the present compound is useful for the treatment of viral myocarditis. Therefore, these references do not provide any motivation for the person skilled in the art to use the present compound for the treatment of viral myocarditis. Moreover, the references do not provide any reasonable expectation of the usefulness of the present compound in the treatment or prophylaxis of viral myocarditis.

In addition, it should be pointed out that Sakai et al. teach the claimed compound to be useful in the treatment of perhaps 100 diseases. The extensive recitation of diseases in the patent is a result of patent drafting technique, not a result of experimentation. One skilled in the art would have doubted the usefulness of the claimed compound in the treatment of so many diseases. At the time of this invention, the claimed compound, as well as the broader class of these compounds, was not known to treat viral diseases. See the teachings of the specification at page 2, lines 13-21. In summary, one skilled in the art would not have had a reasonable expectation of success of the claimed method based upon the teachings of Sakai et al.

In view of the foregoing, it is respectfully submitted that the claims are nonobvious and patentable over the teachings of the cited references. Accordingly, reconsideration and allowance is solicited.

Respectfully submitted,

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